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Ralf Kuchner

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EXAMINER

TANNER, JOCELIN C

ART UNIT

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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,672	Applicant(s) KUEHNER ET AL.	
	Examiner JOCELIN TANNER	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-6, 9-18, 20 and 21 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-6, 9-18, 20 and 21 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This Office Action is in response to the Amendment filed 9 February 2012. Claims 1-6, 9-18, 20 and 21 are currently pending. The Examiner acknowledges the amendments to claims 1, 2, 9-11, 14, 17, 18 and 20 and cancelled claims 22-24.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6, 9-18, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation "pre-enclosed" does not appear to be supported in the instant specification. The specification only discloses in [0029] that in the interior of the supply cylinders a working fluid, in particular Ringer solution, is enclosed in a leakproof manner. Thus, the enclosure may include a valve, or seal or any type of closure that surrounds the working fluid and prevents the working fluid from being expelled prematurely.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Bair (US Patent No. 5,562,692).

3. Regarding claim **20**, Bair discloses a fluid jet surgical cutting tool including a sterile working fluid, a supply chamber (51) capable of pre-enclosing the working fluid, the supply chamber being defined by a movable piston (36), at least one chamber outlet (50) and at least one supply chamber wall; a seal (53) that is capable of hermetically enclosing the sterile working fluid in the supply chamber, the seal capable of irreversibly opening upon application of high pressure (column 3, lines 10-67, column 4, lines 1-35, Fig. 3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4, 6, 9, 12-14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumb et al. (US PGPub No. 2003/0171670A1) in view of Kozam et al. (US Patent No. 4,109,653).

6. Regarding claims **1, 4 and 6**, Gumb et al. disclose an arrangement of a plurality of single-use supply cylinders (5) wherein the supply cylinders being capable of being used during a single occasion or procedure, each supply cylinder including a side wall, a piston (10), working fluid enclosed within each supply cylinder, the working fluid being

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capable of being expelled by the pistons through outlets at the distal end of the syringe before the pressure sensors (2); a single pressure conduit (1) in communication with the outlets of each of the supply cylinders and into which a working fluid is expelled; a plurality of actuation devices (9) to actuate the pistons, and a change-over device that is capable of shifting the actuation from a first piston to the next piston of the plurality of supply cylinders such that the working fluid can be ejected into the pressure conduit from consecutively emptying supply cylinders; a change-over magazine (7) that receives the plurality of supply cylinders, and wherein the change-over magazine defines chambers, each of which receives and closely surrounds the side wall of the respective one of the plurality of supply cylinders ([0016-0018, Figs. 1, 2). However, Gumb et al. fails to expressly disclose the working fluid being enclosed within the cylinder in a leak proof manner.

Kozam et al. teach a device including a syringe or "cylinder"(5) including a one-way valve or "transport gasket" (70, 72) that permits fluid to flow in one direction when fluid is placed under pressure by a plunger or "piston" (18, 20) (column 3, lines 50-67, column 4, lines 1-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the supply cylinders of Gumb et al. with one-way valves, as taught by Kozam et al., to prevent reverse fluid flow and the opening of the valve without the cylinder being under pressure from the pistons.

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7. Regarding claim **2**, Gumb et al. disclose a change-over device that is capable of providing consecutive actuation periods of each of the pistons (10) such that expulsion of the fluid into the single pressure conduit is uninterrupted [0016].

8. Regarding claim **3**, Gumb et al. disclose a sealing device (3) providing leak proof connection to each fluid outlet (Fig. 1).

9. Regarding claim **9**, Gumb et al. disclose the change-over magazine (7) including collection devices (4) to conduct working fluid from the cylinders to the single pressure conduit (Fig. 1).

10. Regarding claim **12**, Gumb et al. disclose the change-over magazine capable of being irreversibly connected to the pressure conduit via hoses (4) to form a single-use unit.

11. Regarding claim **13**, the combination of Gumb et al. and Kozam et al. discloses a plurality of supply cylinders (5) arranged in the change-over magazine (7) that around a central axis of the change-over magazine wherein the central axis is defined by an axis in the center of the magazine between the middle cylinders (Fig. 1a).

12. Regarding claim **14**, the combination of Gumb et al. and Kozam et al. discloses a plurality of cylinders (5) arranged parallel to the central axis of the change-over magazine (Fig. 1a).

13. Regarding claim **16**, Gumb et al. disclose a plurality of supply cylinders that are capable of being individually replaced [0016].

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14. Regarding claim **17**, Gumb et al. disclose a change-over magazine (7) having integrally formed supply cylinders (5) wherein the parts of the device together constitute a whole or complete device (Fig. 1a).

15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gumb et al. (US PGPub No. 2003/0171670A1) in view of Kozam et al. (US Patent No. 4,109,653), as applied to claim 1 above, and further in view of Lee (US Patent No. 5,019,045).

16. Regarding claim **5**, the combination of Gumb et al. and Kozam et al. discloses all of the limitations previously discussed except for a back-flow barrier such that after the piston has reached a position in which the fluid has been expelled from its associated supply cylinder, the piston cannot be pushed back into a previous position.

17. Lee teaches a piston (16) disposed within a cylinder (10) wherein stops or "back-flow barrier" (24) are provided on the inside walls on the body portion (12) such that the piston (16) is prevented from being removed from within the cylinder once advanced past the stops (column 5, lines 1-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Gumb et al. and Kozam et al. with a back-flow barrier, as taught by Lee, to prevent the reuse of the syringe.

18. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gumb et al. (US PGPub No. 2003/0171670A1) in view of Kozam et al. (US Patent No. 4,109,653), as applied to claim 1 above, and further in view of Sielaff et al. (US Patent No. 3,983,864).

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19. Regarding claim **10**, the combination of Gumb et al. and Kozam et al. discloses all of the limitations previously discussed except for ventilation devices for the removal of air from conduit sections located between the outlets of the plurality of supply cylinders and the single pressure conduit.

Sielaff et al. teaches a device including a pump having a cylinder and piston (34a), ventilation devices (38) being located between the outlets of the cylinder of the pump and the pressure conduit (40) (column 5, lines 60-65, column 6, lines 40-67, Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Gumb et al. and Kozam et al. with ventilation devices, as taught by Sielaff et al., to remove any gas before expelling fluid into a body.

20. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gumb et al. (US PGPub No. 2003/0171670A1) in view of Kozam et al. (US Patent No. 4,109,653) in view of Sielaff et al. (US Patent No. 3,983,864) as applied to claim 10 above, and further in view of Childers et al. (US PGPub No. 2004/0019313A1).

21. Regarding claim **11**, the combination of Gumb et al. and Kozam et al. discloses all of the limitations previously discussed except for the ventilation devices being disposed within the change-over magazine.

Childers et al. teach a device including a port vent being integral to a cassette, the port vent being used for venting air purged from the working fluid due to pumping [0038]. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Gumb et

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al., Kozam et al. and Sielaff et al., with ventilation devices within the change-over magazine, as taught by Childers et al., to purge air from the working fluid [0038].

22. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumb et al. (US PGPub No. 2003/0171670A1) in view of Kozam et al. (US Patent No. 4,109,653), as applied to claim 1 above, and further in view of Schwartz et al. (US PGPub No. 2003/0009132A1).

23. Regarding claims **13 and 15**, the combination of Gumb et al. and Kozam et al. discloses all of the limitations previously discussed except for the change-over magazine having a central axis and rotating around the central axis.

24. Schwartz et al. teach a device including a housing (132) having cylinders (44, 46) and a piston (48) disposed and rotatable around the pivot pin (134) located at a central axis ([0085], Fig. 24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the magazine of the device of the combination of Gumb et al. and Kozam et al. to be rotatable about a central axis, as taught by Schwartz et al., to eliminate the need of multiple actuation devices wherein the rotation of the magazine will place the desired piston in contact with the actuation device.

25. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gumb et al. (US PGPub No. 2003/0171670A1) in view of Kozam et al. (US Patent No. 4,109,653) in view of Lee (US Patent No. 5,019,045).

26. Regarding claim **18**, Gumb et al. disclose a device outlet at the distal end of a conduit (1), a plurality of single-use supply chambers (5) capable of pre-enclosing a

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working fluid, a plurality of single-use supply chambers capable of being used during a single occasion or procedure, each supply chamber defined by a piston (10), at least one chamber outlet (4) and at least one supply chamber wall; and the conduit (1) being capable of providing fluid communication between the device outlet and the at least one chamber outlet of each of the plurality of supply chambers ([0016-0018, Figs. 1, 2).

However, Gum et al. fails to disclose a seal that hermetically encloses the working fluid in the supply chamber and a locking mechanism that prevents a return movement of the piston.

Kozam et al. teach a device including a syringe or "cylinder"(5) including a one-way valve or "transport gasket" (70, 72) that permits fluid to flow in one direction when fluid is placed under pressure by a plunger or "piston" (18, 20) (column 3, lines 50-67, column 4, lines 1-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the supply cylinders of Gumb et al. with one-way valves, as taught by Kozam et al., to prevent reverse fluid flow and the opening of the valve without the cylinder being under pressure from the pistons.

Lee teaches a piston (16) disposed within a cylinder (10) wherein stops or "back-flow barrier" (24) are provided on the inside walls on the body portion (12) such that the piston (16) is prevented from being removed from within the cylinder once advanced past the stops (column 5, lines 1-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device

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of the combination of Gumb et al. and Kozam et al. with a back-flow barrier, as taught by Lee, to prevent the reuse of the syringe.

27. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bair (US Patent No. 5,562,692) in view of Lee (US Patent No. 5,019,045).

28. Regarding claim **21**, Bair discloses all of the limitations previously discussed except for the supply chamber including a locking mechanism that prevents a return movement of the movable piston.

Lee teaches a piston (16) disposed within a cylinder (10) wherein stops or "locking mechanism" (24) are provided on the inside walls on the body portion (12) such that the piston (16) is prevented from being removed from within the cylinder once advanced past the stops (column 5, lines 1-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Gumb et al. with a locking mechanism, as taught by Lee, to prevent the reuse of the device.

Response to Arguments

3. Applicant's arguments filed 9 February 2012 have been fully considered but they are not persuasive. The Applicant contends that Bair fails to disclose a pre-enclosed sterile working fluid. However, the supply chamber (51) of Bair receives the working fluid and surrounds or encloses the working fluid therein before expelling the working fluid. The Applicant contends that Gumb et al. fails to disclose a single pressure conduit connected to each of the plurality of supply cylinders. The Applicant contends that each hose (4) of Gumb et al. is connected to the needle (1). The claim requires the pressure

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conduit to be in fluid communication with the outlet of each of the plurality of supply cylinders and does not require direct connection therebetween. Therefore, the supply cylinders (5) of Gumb et al. are shown to be in fluid communication with the single pressure conduit (1) in figure 1a via the hoses (4). The Applicant contends that the working fluid of the combination of Gumb et al. and Kozam et al. is not pre-enclosed within the supply cylinder. However, the working fluid is disposed within a cylinder having a one-way valve that controls the exit of the working fluid such that at any given time the working fluid may be enclosed within the supply cylinder. In response to applicant's argument that the combination of Gumb et al. and Kozam et al. does not disclose an appliance for water jet surgery, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 571-272-4357. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
3/13/2012
Examiner, Art Unit 3731

/Kathleen Sonnett/
Primary Examiner, Art Unit 3731